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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,774 | 10/29/2001 | Alessandra D'Azzo | 2427/1F509-US1 | 9922 |

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| EXAMINER | |
|---|---|
| FRONDA, CHRISTIAN L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/014,774 | D'AZZO | |
| | Examiner | Art Unit | |
| | Christian L. Fronda | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10,13-20 and 22-33* is/are pending in the application.

4a) Of the above claim(s) *1-10,13,18 and 22-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,19 and 20* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 01/28/2005 has been entered.

2. Amended claims 9, 10, and 13 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims recite non-elected subject matter of SEQ ID NO: 4. As stated in the previous Office Action dated 07/28/2004, SEQ ID NO:4 is a patentably distinct sequence having an amino acid sequence that is different from the elected amino acid sequence of SEQ ID NO: 2. SEQ ID NO: 2 and SEQ ID NO: 4 require different searches that are not co-extensive.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9, 10, and 13 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 14-17, 19, and 20 are under consideration in this Office Action.

4. The rejection of claims 14-17, 19, and 20 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, have been withdrawn. Applicants' arguments filed 01/28/2005 are persuasive to overcome these rejections previously applied. The claimed isolated Ozz nucleic acid of SEQ ID NO: 1 is deemed to have a specific, substantial, and credible asserted utility.

### *Claim objections*

5. Claim 14 is objected to because claim 14 depends from non-elected claim 9. Applicant is required to cancel the claim or rewrite the claim in independent form.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of claim 20 encompass any isolated nucleic acid consisting of at least 10 consecutive nucleotides of SEQ ID NO: 1 that hybridizes under the recited stringent conditions, with the proviso that the nucleic acid is not a PPCA exon Ia. In order to meet the enablement requirement, one skilled in the art must be able to make and/or use the invention of claim 20 without undue experimentation using the specification coupled with information known in the art.

However, neither the specification nor the general knowledge of those skilled in the art provide guidance or prediction regarding how to search and screen for the claimed 20 nucleic acid that does not hybridize to the PPCA exon Ia. The general knowledge of those skilled in the art does not provide any guidance or prediction regarding the specific hybridization conditions that would effectively screen out any hybridization to any region of the PPCA exon Ia. Thus, one must perform an enormous amount of trial and error experimentation to determine the specific hybridization conditions that would not result in the claimed nucleic acid hybridizing to any region of the PPCA exon Ia. Such experimentation is undue and well outside of routine experimentation. Teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, one skilled in the art cannot make the invention without undue experimentation and thus, is not enabled by the specification.

8. Claims 15-17, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any vector comprising any nucleic acid of any nucleotide sequence and structure encoding any Ozz protein or fragment of any amino acid sequence and structure. The scope of the claims incluedes many polynucleotides with widely differing structural, chemical, and physical properties. Furthermore, the genus is highly variable because a significant number of structural differnces between genus members exists.

The disclosed polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 1 and a polynucleotide encoding a polypeptide consisting of an amino acid sequence of SEQ ID NO: 2 is not representative of the entire claimed genus since members of the genus include polynucleotides that have structural, chemical, and physical properties that are different from the disclosed Ozz nucleic acid of SEQ ID NO: 1 and SEQ ID NO: 2. The specification does not disclose other representative nucleic acids of the claimed genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v, Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics fo the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

Therefore, in view of the above considerations claim 15 is not adequately described. Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 16, 17, and 19 which depend from claim 15 are also rejected because they do not correct the defect of claim 15.

***Claim Rejections - 35 U.S.C. § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 15-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guan et al. (US Patent 5,643,758; PTO 892) in view of Prinos et al. (Teratology, (1998 Feb) 57 (2) 108). The Prinos et al. reference is attached to the previous Office Action dated 01/30/2004.

Guan et al. teach (1) bacterial, animal, or plant host cells that are transformed with an expression vector containing a polynucleotide encoding a protein fused to the *E.coli* maltose binding protein; (2) methods using said bacterial, animal, or plant host cells in the expression, isolation, and purification of the said protein fused to the *E.coli* maltose binding protein; (3) the advantage that the said methods and host cells can be used in expressing and purifying virtually any polypeptide; and (4) the successful expression, isolation, and purification of beta-galactosidase, PstI restriction endonuclease, and paramyosin using *E.coli* host cells transformed with an expression vector containing polynucleotides encoding the respective proteins (see entire patent, especially column 7, line 51 to column 20, line 40; and Examples I, II, and IV).

Claims 15-17 and 19 differ from the teachings of the reference in that a vector comprises a nucleic acid molecule encoding the full length Ozz protein or a fragment of an Ozz protein.

As stated in the previous Office Action dated 1/30/2004, Prinos et al. teach a cDNA for a mouse homolog of the Drosophila neuralized gene (see entire publication). In absence of facts to the contrary the said mouse homolog of the Drosophila neuralized gene is expected to be capable of binding beta-catenin, myosin, c-Nap, or Alix.

Since the specification states that the claimed protein named as "Ozz" is involved in development and function of muscle and has homology to Drosophila neuralized gene (*neu*) and that the claims do not recite or is limited to a specific nucleotide sequence (SEQ ID NO:); the claims are interpreted as encompassing any nucleic acid encoding any protein involved in development and function of muscle with homology with Drosophila *neu*.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Guan et al. where the cDNA for a mouse homolog of the Drosophila neuralized gene or fragment thereof taught by Prinos et al. is substituted for the polynucleotide encoding a protein molecule in the expression vector taught by Guan et al. to thereby make the vector of claims 15 and 16, which in turn is transfected into a host cell to make the host cell of claim 16. The transfected host cell is then used in the method taught by Guan et al. to make a method for producing the mouse homolog of the Drosophila neuralized gene taught by Prinos et al., where this modified method meets the limitations of claim 19.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to obtain a transformed host cell which can be used in the methods taught by Guan et al. for the expression, isolation, and purification of the mouse homolog of the Drosophila neuralized gene taught by Prinos et al. Furthermore, Guan et al. teach the advantage that the methods and host cells can be used in expressing and purifying virtually any polypeptide.

***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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